

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA-287N] RIN 1117-AB01

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA is hereby proposing to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90- day supply of that controlled substance. DEA is requesting public comment on this proposed rule.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before November 6, 2006.

ADDRESSES: Please submit comments, identified by "Docket No. DEA-287N," by one of the following methods:

1. Regular mail: Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL.
2. Express mail: DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301.
3. E-mail comments directly to agency:
dea.diversion.policy@usdoj.gov.
4. Federal eRulemaking portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

Anyone planning to comment should be aware that all comments received before the close of the comment period will be made available in their entirety for public inspection, including any personal information submitted. For those submitting comments electronically, DEA will accept attachments only in the following formats: Microsoft Word; WordPerfect; Adobe PDF; or Excel.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7297.

SUPPLEMENTARY INFORMATION:

I. Background

On August 26, 2005, DEA published in the Federal Register a "Clarification Of Existing Requirements Under The Controlled Substances Act For Prescribing Schedule II Controlled Substances." 70 FR 50408. That document addressed the situation of patients who have been receiving prescriptions for schedule II controlled substances for legitimate medical purposes (for example, for the treatment of severe pain or attention deficit hyperactivity disorder (ADHD)) and have settled into a routine of seeing their physician once every three months. The document was intended to address the concerns of many such patients who were under the mistaken impression that, because of DEA's November 16, 2004, Interim Policy Statement (69 FR 67170), they had to begin seeing their physicians every month to obtain their schedule II prescriptions. As the August 26, 2005, clarification document noted: "DEA wishes to make clear that the Interim Policy Statement did not state that such patients must visit their physician's office every month to pick up a new prescription." The clarification document further explained some of the possible ways in which, under appropriate circumstances, patients can continue to receive schedule II prescriptions without visiting their physicians' offices every month.\1\

\1\ The clarification document stated, among other things, that a lawfully issued prescription may be mailed by the physician to the patient or pharmacy.

Following the publication of the clarification document, DEA received further comments from the public indicating that many physicians, patients, and pharmacists believe it would still be beneficial to allow physicians to provide individual patients with multiple prescriptions for the same schedule II controlled substance at a single office visit. Those who have commented in favor of allowing this practice suggest that under this approach, the physician would write instructions on each prescription indicating the earliest date on which it could be filled. In this manner, these commenters suggested, a physician should be allowed to authorize up to a 90-day supply of schedule II controlled substances at a single office visit. Other physicians who commented indicated that they do typically see their patients at least once every 30 days for the treatment of pain but that they too believe they should be permitted to issue multiple prescriptions over a shorter time frame (for example, three prescriptions each for a 10-day supply). Physicians who sought to issue multiple prescriptions in this latter manner suggested that doing so would facilitate greater physician oversight and minimize the likelihood of diversion and abuse.

II. Legal Considerations

Whether it is legally permissible for a physician to provide a patient with

multiple prescriptions for a schedule II controlled substance in the manner described above depends on the interpretation given the provision of the Controlled Substances Act (CSA) governing prescriptions, 21 U.S.C. 829. Subsection 829(a) states: "No prescription for a controlled substance in schedule II may be refilled." By comparison, subsection 829(b) states that, for a schedule III or IV controlled substance, a prescription may be refilled up to five times within six months after the date the prescription was issued. Thus, Congress clearly mandated greater prescription controls for schedule II substances than for schedule III and IV substances. For example, a physician may--consistent with the statute--issue a prescription for a schedule III or IV controlled substance and circle on the prescription a certain number of refills. In this manner, a physician may provide a patient with up to a six-month supply of schedule III or IV controlled substance with a single prescription indicating five refills. The same cannot be done with a schedule II controlled substance since section 829(a) prohibits refills. The statute requires a separate prescription if the physician wishes to authorize a continuation of the patient's use of a schedule II drug beyond the amount specified on the first prescription.

Because the statute does not permit refill prescriptions for schedule II drugs, some physicians began over the last decade or so to provide patients with several prescriptions at once, writing "do not fill until [a specified date]" on the additional prescriptions. As noted above, among those physicians who have used this multiple prescription approach, the most common practice has been to give the patient three prescriptions, each for a thirty-day supply, writing on the second prescription "do not fill until [30 days later]" and writing on the third prescription "do not fill until [60 days later]."

Section 829 does not specifically address the practice of issuing multiple schedule II prescriptions. Nor is this practice addressed elsewhere in the [[Page 52725]]

CSA.^{12\} In such situations (when faced with a provision of a statute that does not address the precise question at issue), the agency that administers the statute must interpret it consistent with the text, structure, and purposes of the Act as a whole. The Supreme Court has recently characterized section 829 as a provision that "ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse".^{13\}

^{12\} That the CSA does not address the issuance of multiple schedule II prescriptions is not surprising, since it appears that no physician employed this practice in 1970, when the CSA was enacted. The practice of issuing multiple schedule II prescriptions appears to have begun in approximately 1995.

^{13\} Gonzales v. Oregon, 126 S.Ct. 904, 925 (2006).

Many of the comments that DEA received suggested that the issuance of multiple schedule II prescriptions, under appropriate circumstances, can be beneficial to the practice of medicine and does not promote addiction or recreational abuse. In fact, as discussed above, many commenters asserted that a physician can issue multiple prescriptions in a manner that allows for a greater level of control and supervision to prevent diversion and abuse than if the physician had authorized the same total amount of controlled substances with a single prescription. For example, some commenters said, issuing three ten-day prescriptions with specific instructions on when each should be filled provides for greater control by the physician than a single 30-day prescription for the same total amounts of drugs.

The Supreme Court has held that the administering agency, in order "to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis".¹⁴ DEA has undertaken this task since publishing the Interim Policy Statement. The agency received numerous public comments on this issue. Upon consideration of these comments, DEA is hereby proposing that the issuance of multiple prescriptions in a single visit may be undertaken in a manner consistent with the text, structure, and purposes of the CSA, provided the procedures set forth in this proposed rule are followed.

¹⁴ Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 863-864 (1984).

Before setting forth the proposed rule, it is important to reiterate some additional basic principles: For those patients who have written to DEA stating that they have been receiving prescriptions for schedule II controlled substances for several years (for example, for the treatment of severe pain or ADHD) and have adopted a routine of seeing their physician once every three months, it should be underscored that there is no requirement under the CSA or DEA regulations that such patients must visit their physician's office every month to pick up a new prescription. What is required, in each instance where a physician issues a prescription for any controlled substance, is that the physician properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and that the physician be acting in the usual course of professional practice.¹⁵

¹⁵ 21 CFR 1306.04(a); United States v. Moore, 423 U.S. 122 (1975).

At the same time, schedule II controlled substances, by definition, have the highest potential for abuse, and are the most likely to cause dependence, of all the controlled substances that have an approved medical use.¹⁶ Physicians must, therefore, employ the utmost care in determining whether their patients for whom they are prescribing schedule II controlled substances should be seen in person each time a prescription is issued or whether seeing the patient in person at somewhat less frequent intervals is consistent with sound medical practice and appropriate safeguards against diversion and misuse. Some physicians who submitted comments to DEA indicated that they treat patients for pain or ADHD and believe it is medically appropriate to see the patient in person in every instance where they issue a prescription for a schedule II controlled substance. No physician should view the rule being proposed here as encouragement to see his/ her patients (those who are being prescribed schedule II controlled substances) on a less frequent basis; nor should any physician view this document as signal to be less vigilant for the signs of diversion or abuse. To the contrary, DEA shares the concerns of those physicians whose comments reflect that, in view of the increasingly alarming levels of schedule II drug abuse in the United States, the sound judgment and continuous vigilance of physicians are crucial components in preventing diversion and abuse.

¹⁶ 21 U.S.C. 812(b).

Finally, nothing in this proposed rule changes the requirement that physicians must also abide by the laws of the states in which they practice and any additional requirements imposed by their state medical boards with respect to proper prescribing practices and what constitutes a bona fide physician-patient relationship.¹⁷ As set forth in this proposed rule, the issuance of multiple schedule II prescriptions in the manner described will only be permissible if doing so is also permissible under applicable state laws. Thus, notwithstanding this proposed rule, individual states may disallow the practice of issuing multiple schedule II prescriptions.

¹⁷ 21 U.S.C. 823(f)(1), (4).

Regulatory Certifications *Regulatory Flexibility Act*

The Deputy Administrator hereby certifies that this proposed rule will not have a significant impact on a substantial number of small entities within

the meaning of the Regulatory Flexibility Act (5 U.S.C. 605(b)). This proposed rule would merely provide an additional option that practitioners may utilize when prescribing schedule II controlled substances under certain circumstances. The proposed rule would not mandate any new procedures. Therefore, an initial regulatory flexibility analysis is not required for this proposed rule.

Executive Order 12866

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation. This proposed rule has been determined not to be a "significant regulatory action" under Executive Order 12866, section 3(f). Accordingly, this proposed rule has not been reviewed by the Office of Management and Budget for purposes of Executive Order 12866.

Executive Order 13132

This proposed rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this proposed rule does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 12988--Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$115,000,000 or more in any one year. Therefore, no

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actions are necessary under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not likely to result in any of the following: an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. This proposed rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 804. Therefore, the provisions of SBREFA relating to major rules are inapplicable to this proposed rule. However, a copy of this proposed rule is being submitted to each House of the Congress and to the Comptroller General in accordance with SBREFA (5 U.S.C. 801).

List of Subjects in 21 CFR Part 1306

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Proposed Rule

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, Appendix to Subpart R, the Deputy Administrator hereby proposes that Title 21 of the Code of Federal Regulations, part 1306, be amended as follows:

PART 1306--[AMENDED]

1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

2. Section 1306.12 is revised to read as follows:

Sec. 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) The individual practitioner properly determines there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the individual practitioner is acting in the usual course of professional practice;

(ii) The individual practitioner writes instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill the prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

3. Section 1306.14 is amended by adding a new paragraph (e) to read as follows:

Sec. 1306.14 Labeling of substances and filling of prescriptions.

* * * * *

(e) Where a prescription that has been prepared in accordance with Sec. 1306.12(b) contains instructions from the prescribing practitioner indicating

that the prescription shall not be filled until a certain date, no pharmacist _____
may fill the prescription before that date.

Dated: August 28, 2006.

Michele M. Leonhart,

Deputy Administrator.

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